Comment: Use of Somatic Cells from Deceased Patients

We have a project in which the investigator requested to use stored blood to create iPSC from deceased patients who had their blood collected for clinical hematopietic stem cell transplants but unfortunately died before the reinfusion of their cells. The goal of the project is to study programmed immune system regeneration. The requested cells are ethical and scientifically appropriate for stem cell research for the following reasons:

- Deceased patients had the disease under study
- The research poses no risks to the deceased patients
- The use of blood from deceased patients reduces risks to living patient/donors as using blood from deceased patients reduces the need to collect blood for research purposes from living individuals

Regulatory Issues:

- CIRM regulations at 100080, without exception, require the ESCRO to either ensure that informed consent is provided for the use of the cells or ensure that investigators cannot identify the individual source of somatic cells.

- It is important to maintain links to the deceased patient medical records (with appropriate CA law and HIPAA consideration) in order to understand the medical history when developing the iPSC lines.

- HHS Human Subjects Regulations Do Not Apply: Blood from deceased patients does not constitute human subjects research under 45 CFR 46.102(f) [see below for definition] because deceased patients are not living individuals as defined by the regulation. The regulation defining human subjects does not consider whether the blood is linked to identifiable data such as medical records but rather hinges upon whether the individual is "living". Therefore, IRB review is not required and federal rules for informed consent do not apply for research with materials obtained about deceased individuals.

- The CIRM regulation places an unprecedented and unwarranted impediment on the research as there are no risks to the deceased patients (they are no longer alive to experience risks) and access to such material (blood and medical records) is not covered by the federal regulations for the protection of human subjects.

45 CFR 46.102(f): *Human subject* means a **living individual** [emphasis added] about whom an investigator (whether professional or student) conducting research obtains (1) Data through intervention or interaction with the individual, or (2) Identifiable private information.

It would be helpful if the CIRM rules were consistent with federal regulations for protection of human subjects, in order to facilitate the research, and particularly to assist in national and international collaborations since it appears federal restrictions for stem cell research will change in the next 6 -12 months and many jurisdictions will ensure compliance based on HHS human research rules (at least until specific HHS stem cell rules are promulgated).